

~~66~~  
~~69.~~

A drip chamber in a cerebral spinal fluid (CSF) drainage system comprising:  
a tube having an outer surface; and,  
a vent in fluid communication with the tube, the vent having a filter made of a porous material, the pore size of the filter ranging from greater than .45  $\mu\text{m}$  to about 5.0  $\mu\text{m}$ , the filter being flush with the outer surface of the tube.

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The drip chamber of claim 69 wherein the vent is integral with the outer surface of the tube.

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The drip chamber of claim 69 wherein the porous material is expanded polytetrafluoroethylene (ePTFE).

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The drip chamber of claim 69 wherein the porous material is a hydrophobic material.

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The drip chamber of claim 69 wherein the pore size of the filter is about 3  $\mu\text{m}$ .

#### REMARKS

Claims 1, 3 and 5 have been amended, claims 2, 7 and 13 – 23 have been canceled without prejudice and claims 62 - 73 have been added. Claims 1, 3 – 6, 8 - 12 and 24 -73 remain pending in the application. The Examiner is respectfully requested to re-consider his rejections.

Submitted herewith is a redline version of Figure 7. In the redline drawing, reference number 48 has been added and the lead line from reference number 44 has been changed from a lead line to an arrow. Support for adding the reference number 48 is found in Figure 8. No new matter has been added.

The Examiner has objected to the drawings under 37 C.F.R. 1.83(a) because they fail to show "the filter being flush with the outer surface of the volume reservoir" as described in the claims. Submitted herewith is a redline version of Figure 5 with the label "44" added to show the location of the filter material 44. Support for this addition is found in Figures 6 and 7. As can be seen, filter material 44 is flush with the outer surface of the volume reservoir. No new matter has been added. Therefore, the Examiner is respectfully requested to reconsider his '83(a) objection. Should the Examiner accept the submitted redline versions of Figures 5 and 7, the Applicant will prepare and submit formal drawings for the instant application incorporating the proposed changes.

In the Amendment submitted on October 26, 1999, claims 2 – 61 were added. Apparently, 2 was inadvertently left out. Consequently, for the sake of clarity, claim 2 has been canceled without prejudice and claim 3 has been amended to change its dependency to claim 1.

The Applicants thank the Examiner for the indication of allowable subject matter in claims 23 – 58. Claim 23 has been indicated as being allowed. Since claim 23 is a dependent claim that depends from claim 14, it is believed that the Examiner intended to say that claim 23 is allowable. Claims 14 – 23 have been canceled without prejudice and will be re-filed in a CIP application to the instant application.

No indication of the status of claims 59 – 61 is given in the present Office Action. These claims depend from and further limit the subject matter of the allowed claims 24 – 58. Because these claims depend from and further limit allowed claims, it is respectfully submitted that these claims are also in condition for allowance. Therefore, the Examiner is respectfully requested to also allow claims 59 – 61.

Claim 7 has been indicated as being allowable if rewritten in independent form including all the limitations of the base claim. Claim 7 depends directly from the originally filed claim 5. Claim 5 has been amended to include the limitations of claim 7. Therefore, it is submitted that claim 5 as amended is in condition for allowance. Claims 6 and 8 – 12 depend from and further limit claim 5. Therefore, it is respectfully submitted that claims 6 and 8 – 12 are also in condition for allowance.

Claim 8 has been indicated as being allowable if rewritten in independent form including all the limitations of the base claim. Claim 8 depends directly from the originally filed claim 5. Claim 62 has

been added claiming in independent form the subject matter of originally filed claim 5 and the limitations of claim 8. Therefore, it is submitted that claim 62 is in condition for allowance. Claims 63 – 68 depend from and further limit claim 62. Therefore, it is respectfully submitted that claims 63 – 68 are also in condition for allowance.

Claim 19 has been indicated as being allowable if rewritten in independent form including all the limitations of the base claim. Claim 19 depends directly from originally filed claim 18 that depends directly from the originally filed claim 14. Claim 69 has been added claiming in independent form the subject matter of originally filed claim 14 and the limitations of claims 18 and 19. Therefore, it is submitted that claim 69 is in condition for allowance. Claims 70 – 73 depend from and further limit claim 69. Therefore, it is respectfully submitted that claims 70 – 73 are also in condition for allowance.

Claims 1 – 22 stand rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicants regard as the invention. In particular, the Examiner has stated that it is unclear whether the drip chamber is the same (one piece) as the volume reservoir or is a separate individual part of the drip chamber. In addition, the Examiner has stated that it is unclear if the filter is flush with the outer surface of the volume reservoir from the inside of the volume reservoir or from the outside of the volume reservoir.

Claims 1 and 5 have been amended to remove reference to “volume reservoir” and instead refer to “tube” which is tube 18 in the specification. With this amendment, it is respectfully submitted that the claimed subject matter is particularly pointed out and distinctly claimed. In view of this amendment, the Examiner is respectfully requested to reconsider and remove the ‘112 rejection.

Claims 1-6, 9 – 18 and 21 – 22 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kashmer et al. The Applicant respectfully disagrees.

The Examiner has stated that “Kashmer et al. discloses a drip chamber ...” The Applicant respectfully disagrees. Instead, Kashmer et al. discloses a “suction canister” (title, col. 1, lines 10 – 13). Although, like the instant invention, the purpose of a suction canister is to drain

body fluids from a patient (col. 1, lines 15 – 17), unlike the instant invention, this collection in the Kashmer et al. device is done by using a collection system and a vacuum source such as a pump. (Col. 1, lines 17 – 20) The vacuum source is connected to the canister through a flexible line so that vacuum can be applied to the interior of the canister. (Col. 1, lines 20 – 22) A separate flexible line connects the interior of the canister to a source of body fluids in a patient. (Col. 1, lines 22 – 24) By contrast, the present invention uses no vacuum. Therefore, there is no vacuum source or other related structure in the instant invention.

The problem Kashmer et al. is trying to solve is to provide “a straightforward, easily fabricated system wherein both liquid overflow control and bacteria filtration can be handled by a single control element.” (Col. 1, line 66 – col. 2, line 1) In addition, Kashmer et al. is trying to provide a “mechanism for controlling the liquid overflow ... [that is] ... capable of shutting down the vacuum system which draws liquid into the suction canister.” (Col. 2, lines 1 – 4)

Kashmer et al. solves these problems of vacuum canisters by providing a cover assembly 12 and a receptacle 14. The cover assembly 12 has a suction opening 22 that connects the receptacle 14 to a suction source such as a vacuum. (Col. 4, lines 50 – 60) The cover assembly 12 also has a liquid passage opening 29 that allows a flexible line to be connected at one end to a source of body fluids in a patient and at the other end to the receptacle 14. (Col. 4, line 61 – col. 5, line 1) A valve/filter housing 28 is attached to the suction opening 22. (Fig. 2) The valve/filter housing 28 includes a valve/filter structure 40 that is preferably made of PTFE having a pore size of about 0.5 microns. (Col. 5, lines 21 – 25, col. 6, lines 44 – 49 and col. 7, lines 28 – 46) The valve/filter housing 28 is connected to the source of vacuum.

By contrast to the Kashmer et al. device, all the independent claims 1, 5, 24, 42, 62 and 69 claim: “A drip chamber in a cerebral spinal fluid (CSF) drainage system”. Such drip chambers in CSF drainage systems do not use vacuum pressure to remove fluids from the patient’s body. Instead, the natural intracranial pressure of the cerebral spinal fluid provides the pressure to force excess CSF fluid out of the patient’s brain and into the CSF drainage system. Because there is no vacuum pressure in a CSF drainage system, there is no need for an outlet to connect a reservoir to a source of vacuum pressure and of course, there is no source of vacuum pressure.

Further, the problem to be solved by Kashmer et al., namely, to provide “a straightforward, easily fabricated system wherein both liquid overflow control and bacteria filtration can be handled by a single control element” is completely different from the problem to be solved by the instant application. The problems to be solved by the instant application are:

- 1, A lack of air movement out of the vent causes an “effective airlock” resulting in underdrainage of CSF from the patient. (Page, 4, lines 17 – 20, page 5, lines 13 – 17)
2. A lack of air movement into the vent results in a siphon effect that leads to overdrainage of CSF from the patient. (Page 4, lines 17 – 19, page 4, line 20 – page 5, line 2 and page 5, line 18 – page 6, line 5)

The problem solved by the invention is always relevant and must be considered in determining whether the invention is obvious. In re Wright, 6 USPQ2d 1959, 1961-1962 (Fed.Cir. 1988); Diversitech Corp. v. Century Steps Inc., 7 USPQ2d 1315, 1318 (Fed.Cir. 1988). In fact, the entirety of the claimed invention, including the combination viewed as a whole, the elements thereof, and the properties and purpose of the invention, as well as the solution of a different problem must be considered. In re Wright at 1962. It is respectfully submitted that one skilled in the art trying to solve the problem of allowing proper air movement through a vent in a CSF drainage system would not look to Kashmer et al. which solves a different problem altogether, namely to provide “a straightforward, easily fabricated system wherein both liquid overflow control and bacteria filtration can be handled by a single control element” in a different device, namely a suction canister.

In view of the foregoing, it is respectfully submitted that a “suction canister” such as that disclosed by Kashmer et al. is not analogous art to a CSF drainage system where there is no vacuum used or needed. Consequently, a person skilled in the art of CSF drainage systems would not look to a suction canister with its required vacuum components to solve the problems of CSF systems listed above. Therefore, because there is no recognition in Kashmer et al. of the problem to be solved by the instant invention, because none of the other cited art contains any teaching or suggestion to solve the problem the applicant was trying to solve or any similar problem and because Kashmer et al. is non-analogous art, it is respectfully submitted that Kashmer et al., singly

or in combination with the other cited art, does not anticipate nor render obvious the instant claimed invention.

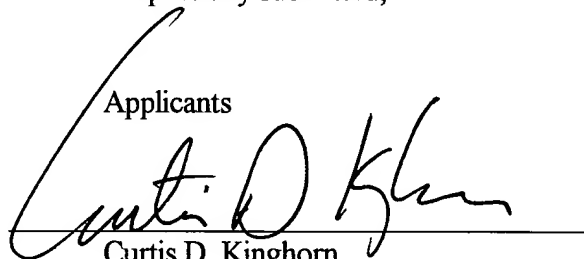
In view of the foregoing, the examiner is respectfully requested to reconsider his rejections. It is respectfully submitted that the claims are in condition for allowance. Therefore, the examiner is respectfully requested to allow the claims.

Should the examiner find it desirable, the examiner is respectfully requested to contact the undersigned at (763) 514-3346 with any comments or questions he may have.

Respectfully submitted,

Applicants

Dated: June 28, 2000

A handwritten signature in black ink, appearing to read "Curtis D. Kinghorn", is written over a horizontal line.

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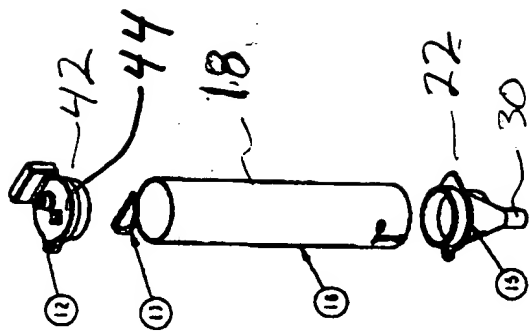
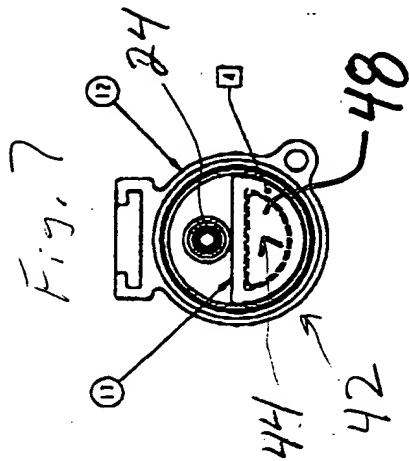


Fig. 5